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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,117	11/30/2000	Robert G. Arther	Mo-6049/MD-00-112-TG	2400
7590 04/09/2007 BAYER CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516-4175			EXAMINER QAZI, SABIHA NAIM	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/727,117

Applicant(s)

ARTHER, ROBERT G.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-12, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**Non Final Office Action**

Claims 9-12, 16 and 17 are pending. No claim is allowed at this time.

**Summary of this Office Action dated March 31, 2007**

1. Continued Examination under CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. Restriction
6. Double Patenting
7. 35 USC § 103(a) Rejection
8. Response to Remarks
9. Communication

**Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/7/2007 has been entered.

**Information Disclosure Statement**

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

**Copending Applications**

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

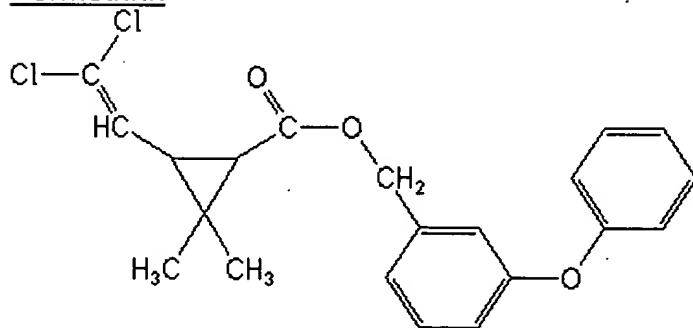
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**Specification**

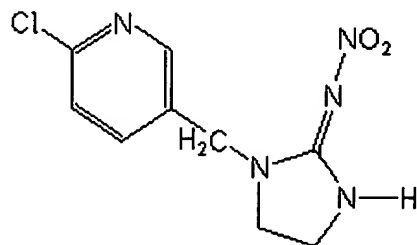
The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

**Restriction**

As per restriction requirement made April 12, 2002, Applicant elected without traverse the claims directed to the combination specific pyrethroid and chloronicotinyl: permethrin and imidacloprid, respectively.

**Permethrin**

and

**Imidacloprid**

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The claims were examined to the extent to the combination of permethrin and imidacloprid. The restriction was made Final. Applicant must amend the claims to the elected invention. Applicant cannot change the elected invention. Process is not the elected invention.

### **Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

*A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).*

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-20 provisionally rejected under the judicially created doctrine of double patenting over claims 4-7 of copending Application No. 10/682127 (Hereinafter

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SIRINYAN et al). This is a provisional double patenting rejection since the conflicting claims have not yet been patented. These applications share a common assignee.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: SIRINYAN et al is drawn to skin-friendly dermally applicable liquid formulations comprising permethrin and imidacloprid for the method of controlling fleas and/or ticks on "warm-blooded animals." The presently claimed invention is drawn to a process for treating a mammal infected with acarids (fleas or mites) comprising dermally administering to the mammal an effective amount of a composition comprising permethrin and imidacloprid.

It would have been obvious to one skilled in the art at the time of invention because warm-blooded animals, as in SIRINYAN et al, is the same as mammals, as in the presently claimed invention.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Claim Rejections - 35 USC § 103---1<sup>st</sup> Rejection**

Claims 9-12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorn et al. (US Patent 6,232,328).

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Dorn et al. teach the combination of pyrethroid and nicotinylic compound specifically imidacloprid and permethrin for the control of parasitic insects such as fleas, lice and flies, which embrace presently, claimed invention. See the entire document especially lines 8-10 and lines 35-68 in col. 17; lines 21 and 22 in col. 18; lines 5-10, lines 25-30 in col. 1; lines 5-10 in column 17 and lines 21 and 22 in column 18. Imidacloprid is disclosed in lines 20-25 column 4 and Permethrin is particularly disclosed in lines 21 and 22 in column 18.

Instant claims differ from the reference in claiming specifically synergistic combination and method of treating wherein prior art teaches that the active compounds can be present in the form of a mixture may be synergists or other active compounds such as pyrethroids etc., see lines 5-10 in col. 17.

*It would have been obvious to one skilled in the art at the time of invention to prepare additional beneficial composition for controlling insects because prior art teaches control of insects by the same combination of compounds as taught by the prior art. Since the synergistic combination is taught by the prior art therefore there is a motivation to prepare the formulation for controlling insects.*

Dorn et al. teaches the combination of pyrethroid and nicotinylic compound for the control of parasitic insects such as fleas, lice and flies. Furthermore, it also teaches that the active compounds can be present in the form of a mixture may be synergists or other active compounds such as pyrethroids etc., see lines 5-10 in col. 17.

The ratio and combination would have been a routine experimentation because it was known that synergism exist between these compounds as taught by the prior art.



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The present specification discloses the combination of a pyrethroid and a chloronicotinyl insecticide which provides enhanced activity against ticks and mites, while maintaining the activity of chloronicotinyl compounds against flees", (lines 20-23 on page 3). Synergistic effect of the combination with chloronicotinylic (imidacloprid) and pyrethroid (permethrin) is disclosed. Since prior art teaches synergistic effect of such combinations, one skilled in the art would expect synergism with any combination such as imidacloprid and permethrin, which has been presently claimed.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

See Ex parte Quadranti where it was held that

"Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

"There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

"Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474

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F.2d 1318, 177 USPQ 139 (CCPA 1973); *In re Klosak*, 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); *In re D'Ancicco*, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. *In re Merck*, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); *In re Freeman*, *supra* .

"Immediately above, we assumed arguendo that the results presented were statistically significant. There is in fact no basis for actually making such an assumption, however. No measure of statistical significance in terms either of P values or confidence limits has been presented. This is particularly important where the differences in question are fairly small, as they are here. The irregular nature of the increase in effectiveness as doubled amounts of Compound IIIb are added also gives rise to questions concerning the reproduceability of the tests used and, thus, the significance of the results. Although patent application specifications are generally not held to the same high standard as scholarly scientific publications, in which statistical significance measures are presented routinely almost as a *sine qua non* , where as here, the data in question are relied on as evidence of unobviousness as it effects the ultimate issue under 35 U.S.C. 103, statistical analysis would unquestionably enhance the probative value of that evidence".

See 201 USPQ 193; *In re Kollman and Irwin*; U.S. Court of Customs and Patent Appeals No.78-624; Decided March 15; 595 F2d 48

It was held that "Appellants point to various examples of data presented in the specification as establishing synergism at other than the 1:1 ratio. This position is not well taken. This data satisfies but part of the criteria set to determine if synergism exists. For instance appellants point to the test in table I employing 4 lbs. of the ether in combination with 2 lbs. of fenac. However there is no testing of the ether at 6 lbs. nor the fenac at 6 lbs., i.e. no testing of the individual components at the total amount of the combination employed.

*The legally accepted definition of synergism as meaning "the combined action of two or more agents \* \* \* that is greater than the sum of the action of one of the agents used alone" is cited in In re Luvisi et al, 144 USPQ 646 . In re Lemin et al, 161 USPQ 288 points out the necessity of presenting data for each component singly at the total rate applied in combination in addition to the fact that each component must be tested individually at the rate at which it appears in combination".*

***Claim Rejections - 35 USC § 103---2<sup>nd</sup> Rejection***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorn et al. (US Patent 6,232,328) in combination of Sirinyan et al (US Patents 6,001,858) and Erdelen et al. (US Patent 5,994,331). These references teach the combination, which embraces presently, claimed invention. See the entire documents.

Dorn et al. teach the combination of pyrethroid and nicotinylic compound specifically imidacloprid and permethrin for the control of parasitic insects such as fleas, lice and flies, which embrace presently, claimed invention. See the entire document especially lines 8-10 and lines 35-68 in col. 17; lines 21 and 22 in col. 18; lines 5-10, lines 25-30 in col. 1; lines 5-10 in column 17 and lines 21 and 22 in column 18. Imidacloprid is disclosed in column 4 lines 20-25. Permethrin is particularly disclosed in lines 21 and 22 in column 18.

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Sirinyan et al. US '858 teaches the combination of imidacloprid and permethrin for the dermal control of parasitic insects. See the abstract, and lines 35-40 in column 4 for imidacloprid and lines 1-2 in column 9 where these compounds are disclosed. See also lines 25-34 in column 8.

Erdelen et al. US '331 teach synergistic combination of chloronicotiny insecticides imidacloprid and various compounds listed in lines 55-68 in column 1 and lines 1-39 in column 2. See claims.

Instant claims differ from the reference in having a broader scope wherein prior art teaches the combination of imidacloprid and permethrin that the active compounds can be present in the form of a mixture may be synergists with other active compounds such as pyrethroids etc., see lines 5-10 in col. 17. Permethrin is particularly disclosed in lines 21 and 22 in column 18.

Since prior art teaches that imidacloprid is synergistic with various pyrethroids and Dorn et al teaches combination of permethrin and imidacloprid may be synergistic one skilled in the art would expect that combination of imidacloprid and permethrin would be synergistic seeing the teaching of prior art.

It would have been obvious to one skilled in the art at the time of invention to prepare additional beneficial composition for controlling insects because prior art teaches control of insects by the same combination of compounds as taught by the prior art. Since the synergistic combination is taught by the prior art therefore there is a motivation to prepare the formulation for controlling insects. The

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combination would have been a routine experimentation because it was known that synergism exist between these compounds as taught by the prior art.

The present specification discloses the combination of a pyrethroid and a chloronicotinyl insecticide which provides enhanced activity against ticks and mites, while maintaining the activity of chloronicotinyl compounds against flees", (lines 20-23 on page 3). The data of the combination with chloronicotinylic (imidacloprid) and pyreththroid (permethrin) is disclosed. Since prior art teaches synergistic effect of such combinations, one skilled in the art would expect synergism with any combination such as imidacloprid and permethrin, which has been presently claimed. Furthermore, The data presented in the disclosure does not show synergism.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

#### **Response to Remarks**

- No response has been filed for the previous action. All the rejections are maintained for the same reasons as set forth in our previous office action.
- Examiner notes, that the elected invention, which was a combination and not the process, has been cancelled. Examiner also notes that election was made without traverse. Process claim is not the elected invention,

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- Data in the specification does not show synergism. Even synergistic combination would have been obvious to one who is familiar with the art because of the reasons cited above.

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D  
PRIMARY EXAMINER